

opposite upper and lower surfaces adapted to be placed in contact with
and to support the adjacent vertebral bodies, said upper and lower surfaces
being non-arcuate;

said opposite sides connecting said upper and lower surfaces and said
leading and trailing ends;

B10
Concl
an opening passing through said upper and lower surfaces for permitting
for the growth of bone from adjacent vertebral body to adjacent vertebral body
through said implant; and

said implant being formed by the process of cutting a section of a long
bone in a direction transverse to the longitudinal axis of the long bone to form at
least a portion of a bone ring and machining said leading end to form said
straight portion.

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- B11
112. (Amended) The implant of claim 111, wherein said lock is made of one of cortical
bone and a bioresorbable material.
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IN THE DRAWINGS:

Please add new Fig. 11 and amend Figs. 4 and 8 to include the changes marked
in red in the Request for Approval of Drawing Changes submitted concurrently herewith.

REMARKS

In the Information Disclosure Statements (IDS) dated June 13, 2000 and
February 5, 2002, Applicant submitted an article attributed to Muschler et al. ("The
Biology of Spinal Fusion;" Spinal Fusion Science and Technique, Cotler and Cotler, pp.

9-13). The Examiner failed to initial the entry next to Muschler et al. in the IDS dated June 13, and crossed out the Muschler et al. entry in the IDS dated February 5. A copy of the February 5 IDS and PTO Form 1449 with a copy of the Muschler et al. article is attached hereto for the Examiner's convenience. Applicant respectfully requests the Examiner to either consider the reference and initial the entry on the Form 1449 or provide an explanation as to why the Muschler et al. submission is not being considered.

Applicant cancelled claims 130-147 without prejudice or disclaimer of their subject matter and amended claims 1, 43, 85, and 112 to further define Applicant's claimed invention. The amendments to claims 1, 43, and 85 are supported by the language of claims 15, 18, and 57 as originally filed, and Figs. 2A, 2B, and 10.

In the Office Action, the Examiner objected to the drawings under 37 C.F.R. § 1.83(a) for not showing every feature of the invention specified in the claims. Applicant respectfully traverses the objection. 35 U.S.C. § 113 (first sentence) states that "the applicant shall furnish a drawing *where necessary for the understanding of the subject matter to be patented.*" (35 U.S.C. § 113 (first sentence) (emphasis added)). Applicant submits that the subject matter of the claims directed to a lock for locking at least one bone screw, the upper and lower surfaces of the implant having at least a second opening passing therethrough, and the composition of the implant material is subject matter that would be understandable to one of ordinary skill in the art without a drawing.

Further, drawings are not usually considered necessary to understand a recitation of a material or composition, or a combination of a material or composition. MPEP § 601.01(f) states that "...situations in which drawings are usually not considered

necessary for the understanding of the invention under 35 U.S.C. 113 (first sentence) are: (A) Coated articles or products...[and] (B) Articles made from a particular material or composition...." (MPEP § 601.01(f), page 600-14, column 2 (August 2001)).

Nonetheless, in order to expedite prosecution, Applicant amended Fig. 8 with representative shading to show that the implant is made of a composite material. Applicant amended Fig. 4 to include reference number 123 to the lock. Applicant added Fig. 11 to the drawings from Fig. 29 of U.S. Patent No. 6,224,607, which is incorporated by reference in the present application on page 3, lines 1-5 of the specification. Fig. 11 shows an implant having at least two openings in each of the upper and lower surfaces. Applicant amended the specification to include a brief description of Fig. 11. The brief description of Fig. 11 is supported by the brief description of Fig. 29 on page 12 of U.S. Patent No. 6,224,607. No new matter has been added. It is submitted that the objection to the drawings has been overcome.

The Examiner also objected to the specification and suggested that patent application numbers mentioned in the disclosure be updated. Applicant has amended the specification at pages 2, 3, and 8 to substitute the patent numbers for U.S. Patent Application Nos. 08/688,758 and 09/490,901. U.S. Patent Application No. 09/457,228 is still pending. It is submitted that the objection to the specification has been overcome.

The Examiner objected to claims 23, 24, 31, 35, 64, 65, 107, 108, and 112 for various informalities. Applicant amended the specification to provide antecedent basis for claims 23, 24, 35, 64, 65, 107, and 108. No new matter has been added. With respect to the objection of claim 31, Applicant respectfully disagrees with the Examiner's

assertion that the combination of bone and composite material is not supported by the specification other than the original claims. The specification at page 5, lines 8-13 refers to a "bone composite" material comprising bone and any other suitable material. Additional support for claim 31 may be found in the specification on page 10, lines 5-8 and page 12, lines 13 and 14. Applicant amended claim 112 to depend from claim 111 as suggested by the Examiner. It is submitted that the objection to claims 23, 24, 31, 35, 64, 65, 107, 108, and 112 has been overcome.

The Examiner rejected claims 1-22, 25-35, 43-63, 66-77, 85-106, 109-119, and 127-129 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,277,149 to Boyle et al. Applicant amended independent claims 1, 43, and 85 to recite that the trailing end of the implant is at least in part curved along "a middle portion" of the trailing end.

Boyle teaches a cortical ring implant with machined sidewalls and curved edges. (Boyle, col. 3, lines 31 and 32; and Fig. 7). Boyle does not teach an implant having a trailing end that is at least in part curved along a middle portion of the trailing end of the implant as claimed by Applicant. Applicant submits independent claims 1, 43, and 85 are allowable and that dependent claims 2-22, 25-35, 44-63, 66-77, 86-106, 109-119, and 127-129 are allowable at least because they depend directly or indirectly from an allowable independent claim.

The Examiner also rejected claims 36-42, 72, 78-84, and 120-126 under 35 U.S.C. § 103(a) as being unpatentable over Boyle and rejected claims 23, 24, 64, 65, 107, and 108 under 35 U.S.C. § 103(a) as being unpatentable over Boyle in view of U.S. Patent No. 5,669,909 to Zdeblick et al. Applicant submits that the Examiner's

rejections of these claims are rendered moot at least in view of the patentability of amended independent claims 1, 43, and 85, which Applicant submits are in condition for allowance. Applicant further submits that dependent claims 23, 24, 36-42, 64, 65, 72, 78-84, 107, 108, and 120-126 are also allowable at least due to their dependency directly or indirectly from independent claims which are allowable over the cited references.

In view of the foregoing amendments and remarks, Applicant respectfully requests the reconsideration and reexamination of this application and the timely allowance of the pending claims.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

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PATENT
Attorney Docket No. 101.0078-00000
Customer No. 22882

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Gary K. Michelson, M.D.)
Serial No.: 09/593,591) Group Art Unit: 3738
Filed: June 13, 2000) Examiner: P. Prebilic
For: MANUFACTURED MAJOR)
LONG BONE RING IMPLANT SHAPED)
TO CONFORM TO A PREPARED)
INTERVERTEBRAL IMPLANTATION)
SPACE)

COPY

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(c)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicant brings to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed after the events recited in Section 1.97(b), but, to the undersigned's knowledge, before the mailing date of either a Final Action or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Information Disclosure Statement is accompanied by a fee of \$180.00 as specified by Section 1.17(p).

The following listed document was previously cited in an Information Disclosure Statement dated June 13, 2000, but not initialed by the Examiner indicating that it has been considered:

Muschler, et al.; The Biology of Spinal Fusion; Spinal Fusion Science and Technique, Cotler and Cotler, pp. 9-13.

Copies of the remaining listed documents are attached.

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claims in the application and applicant determines that the cited documents do not constitute "prior art" under United States law, applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 50-1066.

Respectfully submitted,

MARTIN & FERRARO, LLP

Date: February 5, 2002

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Substitute for FORM PTO-1449	Attorney Docket Number 101.0078-00000	Customer Number 22882	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicant Gary K. Michelson, M.D.	Application Number 09/593,591	
(Use several sheets if necessary) Sheet <u>1</u> of <u>1</u>	Filing Date June 13, 2000	Group Art Unit 3738	Examiner P. Prebilic

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

PBT Muschler, et al.; The Biology of Spinal Fusion: Spinal Fusion Science and Technique, Cotter and Cotter, pp. 9-13.
PCT International Search Report of International Application No. PCT/US01/14844, mailed October 23, 2001.

EXAMINER Paul Prebilis **DATE CONSIDERED** 05-31-03

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.